

(support for this amendment may be found in the Specification at page 17, l. 5-15) and the clause "said composition having a density of from about 0.1 to about 0.5 g/cc" has been added to further describe the embodiment of the composition set forth in the claim (support for this amendment may be found in the Specification at page 7, l. 10-11). Claims 9 and 37 have been amended in order to remove without prejudice the embodiments wherein a "fertilizer" or an "insecticide" is utilized in the compositions of applicants' invention in that these would not be "pharmaceutically active agents". A marked-up copy of the claims as amended is attached hereto as an appendix.

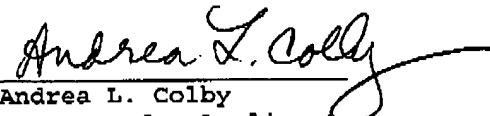
Claims 51 and 56-67 as well as certain language as set forth above have been cancelled without prejudice. Applicants respectfully reserve the right to file claims relating to such subject matter in divisional or continuing patent applications.

Applicants respectfully submit that the claims as amended describe novel, non-obvious compositions in view of the references cited in the Office Action of December 6, 2002. Applicants respectfully submit concurrently herewith a Supplemental Information Disclosure Statement and Supplemental Form 1449 for consideration by the Patent and Trademark Office in connection with this application. The patents cited therein have not been supplied herewith pursuant to discussion with Examiner Wells earlier today.

Based upon the foregoing discussion and amendments to the application, applicants respectfully request reconsideration of the rejections set forth in the Office Action of December 6, 2002.

An early allowance is earnestly solicited.

Respectfully submitted,


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MARKED-UP CLAIMS AS AMENDED

1. (Twice Amended) A [freeze-dried] composition wherein said composition is a freeze-dried composition comprising:

(a) a sustained release layer comprising:

(i) a water-soluble polymer; and

(ii) a first pharmaceutically active agent; and

(b) adjacent said sustained release layer, a fast release layer comprising:

(i) a matrix forming agent; and

(ii) a second pharmaceutically active agent;

[said composition being made by the process comprising:

(a) adding said water-soluble polymer and said first pharmaceutically active agent to water to form a first aqueous solution;

(b) adding said matrix forming agent and said second pharmaceutically active agent to water to form a second aqueous solution;

(c) combining said first and said second aqueous solutions in a container to form a combined solution;

(d) rapidly freeze-drying said combined solution; and

(e) lyophilizing said combined solution]

said composition having a density of from about 0.1 to about 0.5 g/cc.

2. (Amended) A composition as defined in claim 1, wherein the water-soluble polymer is selected from the group consisting of celluloses, cellulose ethers, polycarboxylated vinyl polymers, polyurethanes, gelatins, polysaccharide gums, seed gums, crosslinked alginate gum gels, and [any] combinations [of any of the foregoing] thereof.

3. (Amended) A composition as defined in claim 2, wherein the polycarboxylated vinyl polymer is selected from the group consisting of polyacrylic acid polymers, [polyacrylic] polyacrylic acid polymers

4. (Amended) A composition as defined in claim 2, wherein the polysaccharide gum is selected from the group consisting of karaya gum, ghatti gum, and combinations [of any of the foregoing] thereof.

5. (Amended) A composition as defined in claim 2, wherein the seed gum is selected from the group consisting of guar gum, locust bean gum, psyllium seed gum, and [any] combinations [of any of the foregoing] thereof.

6. (Amended) A composition as defined in claim 2, wherein the water-soluble polymer is selected from the group consisting of polyurethanes, gelatins, hydroxypropylmethylcellulose, sodium carboxymethylcellulose, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxethylmethylcellulose, hydroxyethylethylcellulose, hydroxypropylethylcellulose, carbopol, polyvinyl alcohol, dextran, chitosan, starches, polyacrylamides, polyacrylates, agar, collagen, fibronectin, alginic acid, pectin, hyaluronic acid, and combinations [of any of the foregoing] thereof.

9. (Amended) A composition as defined in claim 1, wherein the first pharmaceutically active agent is selected from the group consisting of an anti-fungal agent, an anti-bacterial agent, a nutrient, a vitamin, a mineral, a diagnostic, [a fertilizer, an insecticide,] or [any] combinations [of any of the foregoing] thereof.

10. (Amended) A composition as defined in claim 1, wherein the first pharmaceutically active agent is selected from the group consisting of metronidazole, miconazole nitrate, terconazole, chlorpheniramine maleate, pseudoephedrine, dextromethorphan, meclizine dihydrochloride, haloperidol, albuterol sulfate, dimenhydrinate, benzodiazepines, and [any] combinations [of any of the foregoing] thereof.

polypeptide/polysaccharide complexes, sugars, inorganic salts, amino acids having from about 2 to about 12 carbon atoms, and [any] combinations [of any of the foregoing] thereof.

28. (Amended) A composition as defined in claim 27, wherein the animal or vegetable protein [derivative] is selected from the group consisting of gelatins, [dextrins] dextrins, soy, wheat end psyllium seed proteins, and [any] combinations [of any of the foregoing] thereof.

29. (Amended) A composition as defined in claim 27, wherein the gum is selected from the group consisting of acacia, guar, agar, xanthan[m], and [any] combinations [of any of the foregoing] thereof.

33. (Amended) A composition as defined in claim 27, wherein the amino acid is selected from the group consisting of glycine, L-alanine, L-aspartic acid, L-glutamic acid, L-hydroxyproline, L-isoleucine, L-leucine, L-phenylalanine, and [any] combinations [of any of the foregoing] thereof.

35. (Amended) A composition as defined in claim 27, wherein the matrix forming agent is selected from the group consisting of gelatin, pectin, soy fiber protein, and [any] combinations [of any of the foregoing] thereof.

37. (Amended) A composition as defined in claim 1, wherein the second pharmaceutically active agent is selected from the group consisting of an anti-fungal agent, an anti-bacterial agent, a nutrient, a vitamin, a mineral, a diagnostic, [a fertilizer, an insecticide,] or [any] combinations [of any of the foregoing] thereof.

38. (Amended) A composition as defined in claim 1, wherein the second pharmaceutically active agent is selected from the group consisting of metronidazole, miconazole nitrate, terconazole, chlorpheniramine maleate,